

REMARKS

Claims 1 to 4 and 25 to 54 are pending in this application. Claims 3, 4, 25 to 37, 39 to 42, 46 to 50 and 52 have been allowed. Claims 1, 2, 38, 43 to 45, 51, 53 and 54 have been rejected under 35 U.S.C. section §103(a). None of the claims have been amended in this submission.

Rejection Under U.S.C. §103(a)

Claims 1, 2, 38, 43 to 45, 51, 53 and 54 have been rejected under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent No. 6,057,165 to Mansour (hereinafter "Mansour") in view of U.S. Patent No. 6,720,191 to Goldstein et al. (hereinafter "Goldstein"). Applicants respectfully traverse this rejection. Applicants have fully addressed the contents of Mansour in their Amendment Under 37 C.F.R. §1.111, which was filed January 20, 2005 (the arguments of which are incorporated herein by reference in their entirety). Applicants address below the Office's new proposed combination of Mansour with Goldstein. It is applicants' position that no skilled practitioner would have been motivated to combine the disclosures of Mansour and Goldstein and, even if for some reason they did so, the resulting combination would not yield the presently claimed combination.

1. Requirements for a *prima facie* case of obviousness

"To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure." MPEP §2143.

2. There is no suggestion or motivation to combine or modify the prior art because the proposal renders the modified prior art unsatisfactory for its intended purpose

The Office has failed to meet the first criterion for establishing a *prima facie* case of obviousness. The first criterion requires some suggestion or motivation, either in the references themselves or in the knowledge generally available to skilled practitioners, to modify the reference or to combine reference teachings. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Circ. 1984), and the MPEP section that discusses it (MPEP §2143.01(V)), appear relevant here. The MPEP section states (emphasis added):

If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Circ. 1984). (Claimed device was a blood filter assembly for use during medical procedures wherein both the inlet and outlet for the blood were located at the bottom end of the filter assembly, and wherein a gas vent was present at the top of the filter assembly. The prior art reference taught a liquid strainer for removing dirt and water from gasoline and other light oils wherein the inlet and outlet were at the top of the device, and wherein a pet-cock (stopcock) was located at the bottom of the device for periodically removing the collected dirt and water. The reference further taught that the separation is assisted by gravity. The Board concluded the claims were *prima facie* obvious, reasoning that it would have been **obvious to turn the reference device upside down**. The court reversed, finding that **if the prior art device was turned upside down it would be inoperable for its intended purpose** because the gasoline to be filtered would be trapped at the top, the water and heavier oils sought to be separated would flow out of the outlet instead of the purified gasoline, and the screen would become clogged.).

The modification proposed by the Office in the present case suffers a deficiency similar to that proposed by the Office in *Gordon*. The proposed modification changes the Mansour device into a non-flow-through device, thereby rendering it unsatisfactory for its intended purpose. There is no suggestion or motivation to make the proposed modification in the cited art and thus a *prima facie* case of obviousness has not been established. The problems associated with attempting to combine Mansour and Goldstein are discussed in detail below.

3. The Office's proposed modification/combination of the prior art

The Office states as follows (at page 3; emphasis added):

Mansour differs from the instant invention in that the amended claims recite that the carrier closes the first opening so that fluid flow is prevented through the bottom surface of the carrier.

The Office (at page 3, emphasis added) proposes the following modification:

Goldstein et al. teach an alternative carrier to the absorbent carrier disclosed in Mansour. It would have been obvious to one of ordinary skill in the art to incorporate the pressure-sensitive adhesive carrier into the carrier receiving device of Mansour to provide a means of capturing and analyzing a different type of sample (such as a solid sample) that would not be possible with the absorbent carrier disclosed by Mansour. Such modification would involve mere substitution of one known type of carrier as discussed in MPEP 2144.07.

Thus, the Office proposes to modify Mansour by substituting the adhesive carrier of Goldstein for the carrier in Mansour to enable the capture of solid samples. This statement is evidence of impermissible hindsight used by the Office because there is no disclosure, teaching or suggestion in Mansour to capture and analyze solid samples. Because Mansour did not contemplate capturing and analyzing something outside the scope of its invention, there can be no teaching or suggestion found in Mansour to the contrary. The teaching or suggestion to make the claimed combination must be found in the prior art not in applicant's disclosure. MPEP §2143. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). That which the Office states is not possible to accomplish in the prior art is part of the subject matter of novelty of the present invention. Mansour does not disclose, teach or suggest using a different type of sample such as a solid sample. For these reasons, the present invention is not obvious.

The Office's proposed modification changes Mansour into a non-flow-through device. This modification renders Mansour useless for its intended purpose as a flow-through device. In support of this assertion, applicants will show (1) that Mansour is a flow-through device, (2) that Goldstein's adhesive carrier does not allow reagents to flow through, (3) that the proposed modification would change Mansour into a non-flow-through device, (4) that such a modification would require substantial reconstruction and redesign of the structural elements

shown in Mansour, (5) that such a modification would also change the functional features of Mansour and the basic principle under which the Mansour construction was designed to operate, (6) that the proposed modification requires substantial reconstruction and redesign of the structural elements shown in Goldstein, and (7) that such modification would also change the functional features of Goldstein and the basic principle under which the Goldstein construction was designed to operate. For all these reasons, the independent claims and their respective dependent claims are nonobvious and in a condition for allowance.

4. Mansour is a flow-through device

The device in Mansour is a flow-through device. The title of the Mansour patent is "Quality control procedure for membrane flow-through diagnostic assay devices." The Mansour specification states that "[a] need has existed for a flow-through assay device..." Mansour, col. 3, lines 3-4. A look at the Mansour claims reveals several limitations that require flow-through of liquids. And, the previous responses to Office Actions have pointed out citations where flow-through in Mansour is required. It is clear that the purpose of Mansour is to provide a flow-through device.

5. Goldstein's adhesive tape is not a flow-through material

In contrast to the flow-through device of Mansour, there is no disclosure, teaching or suggestion in Goldstein of a flow-through device. There is also no disclosure, teaching or suggestion in Goldstein for any reagent to flow through the Goldstein carrier. In fact, Goldstein teaches away from the Office's proposed combination by disclosing a non-porous adhesive film (e.g., EVA polymer). Goldstein, col 1, line 28. In one embodiment, Goldstein discloses a strip of tape substrate. "[C]oated tape 18A is shown constructed from, e.g., polyester films such as Mylar® having discrete and spaced apart coated spots 52 placed on coated side 19 of the tape." Goldstein, col.7, lines 53-56. The coated tape does not permit flow-through of reagents. It is clear that Goldstein does not disclose, teach or suggest a porous coating, tape, substrate or other carrier that would permit reagent to flow through.

6. The Office's proposed modification/combination would change Mansour into a non-flow-through device.

The Office's proposed modification is to take the Goldstein adhesive and substitute it for the carrier in Mansour. As shown above, Mansour is a flow-through device and Goldstein's tape is not. Hence, modifying Mansour to incorporate the tape of Goldstein into Mansour would no longer make Mansour a flow-through device and would render Mansour useless for its intended purpose as a flow-through device. *Because the proposed combination/modification by the Office changes the Mansour device into a non-flow-through device, the invention is thereby rendered unsatisfactory for its intended purpose.* Therefore, there is no suggestion or motivation to make the proposed modification and a *prima facie* case of obviousness is not established.

7. There is no suggestion or motivation to combine or modify the prior art because the proposed modification/combination requires a substantial reconstruction and redesign of the elements of Mansour

The flow-through concept of Mansour is an important feature of Mansour that cannot be negated. The flow-through structural features in Mansour include (1) an absorptive layer 44, (2) a porous spacer layer 43, (3) a flow control layer 42, (4) a porous membrane 41 and (5) teeth-like projections 49 to provide air spaces 50 for ventilation in the Mansour carrier. Making the modification/combination to Mansour as proposed by the Office would not only make Mansour no longer a flow-through device but also, doing so would render at least all five of the above-listed structural features entirely useless and, as a result, would render the Mansour invention unsatisfactory for its intended purpose. Hence, making the proposed modification does not merely include a mere substitution as stated by the Office, but involves a complete restructuring of the Mansour carrier to remove the absorptive layer 44, remove the porous spacer layer 43, remove the flow control layer 42, remove the porous membrane 41 and redesign the Mansour carrier to remove the projections 49 and air spaces 50. The suggested combination of references would require a substantial redesign of the elements shown in the primary reference as well as a

change in the basic principle under which the primary reference was designed to operate. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. MPEP §2143.01(VI).

8. There is no suggestion or motivation to combine or modify the prior art because the proposed modification/combination changes the principle of operation of the prior art

Not only are the structural features of Mansour negated by the Office's proposed modification as illustrated in the above paragraph, but also, various functional features served by the Mansour device would also be negated. Negation of these functional features changes the principle of operation of Mansour. For example, Mansour states (at col. 5, lines 10 to 13):

The absorbent layer also functions to provide a driving force (e.g., a concentration differential) which causes reagents applied to the test area of the assay device to flow into the absorbent layer.

Providing a driving force for fluids is a functional feature of the absorbent layer. This functional feature is completely changed by the Office's proposed modification/combination. Hence, the function of a driving force provided by the absorbent layer is negated by the Office's proposed modification which changes the principle of operation of Mansour. As a result of the modification, the Mansour device no longer operates such that a driving force is provided by the absorbent layer. As a result, there is no driving force at all. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. MPEP §2143.01(VI).

Yet another functional feature of the Mansour device that is negated by the Office's proposed modification is flow-through of unbound tracer. Mansour at col. 5, lines 18-24 states:

In addition, since the assay composite is employed in a manner such that the assay reagents flow through its layers, the porous membrane has a pore size which is greater than the size of the particulate label employed in the assay so that portions of the tracer, which do not become bound under assay conditions, flow into the absorbent layer and are not visible at the test area.

A part of the basic principle of operation of the Mansour device is to allow tracer that is not bound to the binder to flow through into the absorbent layer. An advantage of this basic principle of operation is that excess tracer is not visible at the surface test area. The Office's proposed modification/combination does not take into consideration this functional feature which would be lost by the proposed modification. Hence, not only the structural feature of the Mansour device as a flow-through device is negated by the Office's proposed modification but also, the functional feature of the Mansour device is negated. Therefore, a *prima facie* case is not established.

Still, another basic principle of operation of the Mansour device that would be changed by the Office's proposed modification is the control of the rate of flow of reagents. Mansour states (at col. 5, lines 35 to 41):

Thus, in effect, the flow control layer functions to reduce the rate of flow of assay reagents through the more porous test area. The pore size of the flow control layer, as well as the thickness of the flow control layer, is preferably controlled in a manner such that the flow of assay reagents through the test area provides the requisite sensitivity as well as a rapid and accurate assay.

There is no other disclosure, suggestion, or motivation for how to otherwise meet the basic operation of Mansour to control the flow rate of fluids to provide the requisite sensitivity as well as a rapid and accurate assay. Because Mansour's intended purpose of controlling the flow rate is negated, there can be no suggestion or motivation for the Office's proposed modification and a *prima facie* case is not established.

Additional steps in Mansour's invention are rendered useless by the Office's proposed modification. These steps include, e.g.,:

- (1) The flow through of tracer discussed above.
- (2) The flow through of wash solution ("Similarly, after addition of the tracer, a wash solution may be applied to the test area 60 to wash any tracer which may not be specifically bound to the complex in the test area 60, into the absorbent layer 44." Mansour, col. 12, lines 14-17.).

- (3) The flow through of sample (“...the analyte positive control sample contacts all of the binder in the test area 48, with the sample flowing through to the absorbent layer 44.” Mansour, col. 12, lines 28-29.).

These above-listed steps would serve no function as a result of the Office’s proposed modification. As a result, the basic principle of operation of Mansour changes such that there is no flow through of reagents. There is nothing in the prior art to disclose, teach or suggest the changes to be made. Therefore, there is no suggestion or motivation to make the proposed modification/combination and, as such, no *prima facie* case of obviousness has been established.

9. There is no suggestion or motivation to combine or modify the prior art because the proposed modification/combination requires a substantial reconstruction and redesign of the elements of Goldstein

Applicants would also like to point out that the Office’s proposed modification/combination would require a substantial reconstruction and redesign of the elements of Goldstein. Firstly, there is no disclosure, teaching or suggestion in Goldstein to fashion the Goldstein carrier into something that would fit the Mansour device. Secondly, if the Goldstein carrier was fashioned into something that would fit the Mansour device, it would require reconstruction and redesign of the Goldstein carrier. For example, in one embodiment of the Goldstein carrier, the carrier is a tape which is flexible and flimsy. It would have to be adapted such that it would snap to the Mansour cover.

In another embodiment, the Goldstein carrier is a spoke which is broken off (see FIGs. 8 and 12). To adapt this embodiment of the Goldstein carrier to fit the Mansour cover would require substantial reconstruction and redesign not only of the broken off piece but also, of the basic principle of operation of the daisy wheel which is used for obtaining sequential transfers in Goldstein. The principle of operation of Goldstein which involves breaking off pieces to carry them to analysis would be changed because it is highly unlikely that a broken off piece would suitably fit the Mansour cover. Hence, even use of a daisy wheel and the step of breaking off a piece, both principles of operation, would have to be changed.

In yet another embodiment, the Goldstein carrier is a comb with comb fingers. To adapt this embodiment of the Goldstein carrier to fit the Mansour cover would require substantial reconstruction and redesign not only of the carrier but also of the basic principle of operation of obtaining samples using the comb instrument. All of these examples show that Goldstein, in fact, teaches away from the making the modification proposed by the Office.

10. The prior art does not teach or suggest all of the claim limitations

To establish a *prima facie* case of obviousness, the prior art must teach or suggest all of the claim limitations. The prior art does not disclose, teach or suggest all of the claim limitations. In particular, as discussed in applicants' previous Amendment, Mansour does not disclose, teach, or suggest at least the claim limitation of preventing fluid flow across the chamber and carrier interface. Goldstein does not provide the information missing from Mansour.

Mansour teaches away from this limitation by disclosing a flow-through device. Fluid flows out of the reservoir in Mansour through a system of porous and flow control layers. "The assay composite 40 is comprised of a porous membrane 41..." Mansour, col. 11, lines 7-8. The porosity of the composite is discussed in Mansour at col. 11, lines 5-17. "Adjacent to the lower surface of the porous membrane 41 is a flow control layer 42 which is preferably formed from a unidirectional flow-controlling polycarbonate membrane having a pore size of 0.6 micron." Mansour, col. 11, lines 14-17. "Immediately underneath the flow control layer is a porous spacer layer 42 which generally has a pore size greater than the pore size of flow controlling layer 42." Mansour, col. 11, lines 18-20. "Immediately underneath the porous spacer layer 43 is absorptive layer 44." Mansour, col. 11, lines 22-23.

Clearly, in Mansour the reservoir is not sealed and fluid is allowed to flow through the various porous and flow-control layers. Actually, there is nothing even beyond the absorptive layers to further contain fluid flow within the reservoir at that end. In fact, spaces are provided to ventilate the assay composite 40. See Mansour at col. 11, lines 46-50 ("The cover 46 is supported over porous membrane 41 by teeth-like projections 49 extending upward from the

sides of the base 45. The projections 49 are of sufficient height to provide air spaces 50 which provide for ventilation of the sides of the assay composite 40.”). Mansour’s device peculiarly ventilates the assay composite which according to the Office is an equivalent to the sample. In such a construction, fluid flows into, through, and past the sample and even possibly beyond them and through the spaces 50 in Mansour. Therefore, Mansour is quite different from applicants’ invention as claimed.

The Office appears to acknowledge Mansour’s deficiencies as a prior art reference at page 3 of the present Office Action, saying:

Mansour differs from the instant invention in the the amended claims are recite that the carrier closes the first opening so that fluid flow is prevented through the bottom surface of the carrier. Mansour discloses an absorbent multi-layered carrier that would allow flow through the absorbent layers.

However, the Office appears to believe this deficiency would somehow be remedied by Goldstein. Applicants disagree. Nowhere does Goldstein disclose, teach, or suggest this claim element. The mere fact that Goldstein or any other reference discloses some material, e.g., Goldstein’s tape, that could conceivably be reconstructed and placed into Mansour’s device in an attempt to replace Mansour’s absorbent layer does not satisfy this limitation.

In view of the foregoing remarks, applicants respectfully submit that neither Mansour nor Goldstein, alone or in combination, renders claims 1, 2, 38, 43 to 45, 51, 53 and 54 obvious. Thus, applicants respectfully request that the present rejection be reconsidered and withdrawn. The Office is invited to contact the applicant’s representative at the number below to facilitate prosecution of this application.

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Page : 12 of 12

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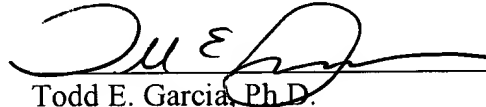
CONCLUSION

Applicants submit that all pending claims are now allowable and respectfully request a notice of allowance. Enclosed is a \$120 check for the Petition for Extension of Time fee, along with a Petition for a One Month Extension of Time. No excess claims fees are believed to be due. Please apply any other charges or credits to deposit account 06-1050, referencing Attorney Docket No. 14255-036001.

Respectfully submitted,

Date: _____

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